

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The claims are drawn to a liquid composition comprising follicle stimulating hormone and poloaxmer 188.

The references of Lee et al. teaches that the use of cresol and phenol favored aggregation when combined with insulin. The reference further teaches that aggregation can be prevented by addition of poloaxmer 188 and PEG (see page 35). The reference of Katakam et al. teach stabilization of human growth hormone from aggregation using poloaxmer 188, where the aggregation is a result of vortex mixing or multiple passages through a hypodermic needle.

None of the reference fairly teach nor suggest the claimed invention. The instant claims are drawn to FSH formulations with poloaxmer 188. None of the references teach nor suggest formulations comprising FSH. Furthermore, none of the references cited nor the prior art as a whole teaches that FSH, when mixed with cresol or phenol, results in gellation or aggregation similar to insulin. Similarly, none of the references cited, nor the prior art as a whole, suggest aggregate formation from vortex mixing or passages through a hypodermic needle of FSH formulations. Accordingly, one of ordinary skill in the art would not use the teachings of either Lee or Katakama for motivation to combine FSH formulations with poloaxmer 188. The claims are both novel and unobvious over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/  
Primary Examiner, Art Unit 1654